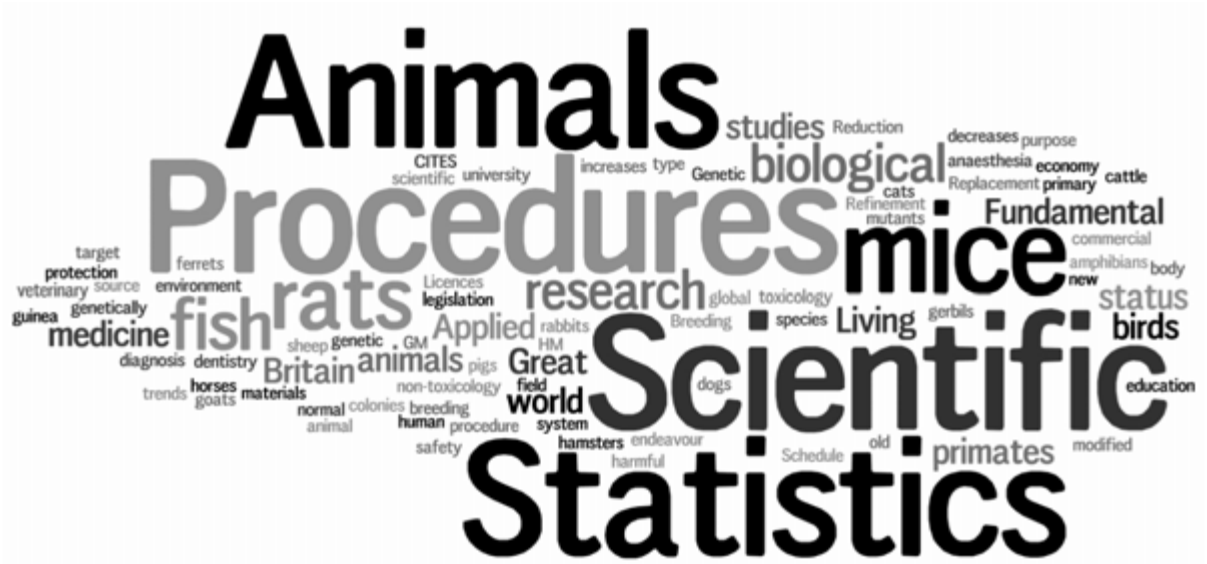
Home Office

User Guide to Home Office Statistics of Scientific Procedures on Living Animals

Last updated: July 2014



CONTENTS

Introduction

1.1 This user guide accompanies the Home Office publication 'Annual Statistics of Scientific Procedures on Living Animals, Great Britain 2013'.

Coverage

1.2 The statistics in the publication relate to scientific procedures performed using living animals subject to the provisions of the Animals (Scientific Procedures) Act 1986.

Purpose of the collection

1.3 In the UK the use of animals in scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986, an animal protection measure that requires licensing and oversight of all places, projects and personnel involved in such work. Under the 1986 Act the Home Office must inform Parliament of the authorised annual use made in Great Britain of animals in scientific procedures (separate information is produced for Northern Ireland under devolved arrangements). This is done through the presentation of a detailed annual statistical report.

1.4 Formally the purpose of the publication is to meet the requirements of the Animals (Scientific Procedures) Act 1986 section 21(7) "The Secretary of State shall in each year publish and lay before Parliament such information as he considers appropriate with respect to the use of protected animals in the previous year for experimental or other scientific purposes". The system of control under the 1986 Act is explained in detail in Appendix A of the annual publication.

1.5 The data collection (along with corresponding collection of data for Northern Ireland by DHSSPS) enables the UK to meet requirements for data to be supplied to the EU. The latest EU (seventh) report provides an overview on the number of animals used in the EU in 2011for experimental and other scientific purposes. The EU report includes data from all 27 Member States, submitted in the agreed format by all countries and is available at http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm.

1.6 The objective of the (EU) report is to present to the European Council and European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

Confidentiality and data quality

1.7 Detailed information on the work of individual project licence holders is not readily identifiable in the annual statistics. Where a further breakdown of the 'other' species categories are not given in the commentary this is to safeguard the confidentiality of the establishment and the licence holder.

Revisions to data

1.8 Data for the latest calendar year may be revised in due course. It is the authors' standard practice to incorporate revisions for previous years in the latest release. Corrections and revisions follow the Home Office corporate revisions policy: https://www.gov.uk/government/publications/statement-of-compliance-with-code-of-practice-for-official-statistics, page 5.

Revisions analysis

1.9 There have been no revisions to the 2012 figures first published in July 2013. Any errors in the 2012 returns were discovered in time to be corrected in the July 2013 report. There have been no subsequent re-submissions.

Acknowledgements

1.10 This publication has been prepared by staff in the Home Office Statistics unit of the Home Office Science Group. They are grateful for the support of colleagues in Policing Data Collection Section for data input, the Animals in Science Regulation Unit for their assistance with the collection, processing and quality assurance processes involved in preparing the report, and colleagues in the Communications Development Section who assisted in preparing the report for publication. Last but not least, the contribution of licensees who provide the returns used to compile the annual statistical report is also acknowledged.

Further information available

1.11 The following information is available from the Internet site https://www.gov.uk/government/organisations/home-office/series/statistics-of-scientific-procedures-on-living-animals

- the bulletin 'Annual Statistics of Scientific Procedures on Living Animals Great Britain';
- the accompanying 'Supplementary Tables' and the 'Time Series Tables'; and
- this document 'User Guide to Home Office Statistics of Scientific Procedures on Living Animals'.

1.12 The dates of future editions are pre-announced and can be found via the UK National Statistics Publication Hub: http://www.statistics.gov.uk/hub/release-calendar/index.html

Home Office Responsible Statistician

David Blunt, Chief Statistician and Head of Profession for Statistics

1.12 Information on how Home Office Statistics outputs are published independently as part of the Code of Practice for Official Statistics is available at http://homeoffice.gov.uk/science-research/about-home-office-science/official-statistics/

Enquiries

1.13 If you have any enquiries about this publication, please email asp.statistics@homeoffice.gsi.gov.uk or write to:

Policing and Other Section, Home Office Statistics, 1st Floor, Peel Building, 2 Marsham Street, London, SW1P 4DF.

Definitions, presentation and classification

Introduction and counting rules

2.1 The statistics are compiled from forms submitted by project licence holders at the end of each year, or on the termination of the licence when this occurs during the year. A copy of the form notes can be found in this user guide (see para 6.1 below), including the detailed definition of a procedure, and descriptions of the standard coding lists used for describing procedures. The legal definition of a procedure (which applied up to the end of 2012) appears in para 2.11 below.

2.2 Each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it commenced. A study involving a procedure using a number of animals is counted once for each animal. Where an animal that has recovered fully from a completed procedure is used again for a further procedure it is counted as a separate procedure, but the animal itself is not re-counted. The circumstances in which this re-use of an animal is permitted are limited.

Presentation of the data

2.3 The figures given in the annual statistics publication refer to the numbers of procedures that were started in the latest calendar year, rather than the numbers of animals, compared with the previous calendar year, unless indicated otherwise.

2.4 Figures in the annual statistics publication 'Summary and Commentary' have sometimes been rounded to the nearest 1000 or 100 procedures or to 2 significant figures, depending on the size of the figures in a particular section of commentary. For given sections, all figures are presented in an unrounded form where some figures are less than 1,000 and all figures are presented to the nearest 100 where all figures are in their thousands. All figures in millions are presented as millions to two decimal places (e.g. 4.36 million). This practice is taken in order to simplify the explanation/ presentation; therefore the figures shown will not be identical to the figures in the tables. However, percentage changes given are calculated using the unrounded data available in the tables.

2.5 The data presented in the tables and commentary in the annual statistical publication, relate to either:

- the number of procedures started in the year - most tables (adult animals only i.e. excluding foetal, larval or embryonic animals); or

- the number of animals used for the first time - tables appended with suffix 'a' e.g. Table 1a, Table 6a, Table 9a (as part of the procedures started in the year, adult animals only)

2.6 In most cases the number of procedures started corresponds to the number of animals used. Where the number of procedures started is higher than the number of animals used, then by implication there has been re-use of animals.

Non-countable procedures

2.7 It is impracticable to collect accurate figures on the number of animals affected in field trials of rodenticide substances. Such field trials are rare (e.g. there was one return from a licensee that indicated that such field trials occurred in the calendar year 2010 as part of the work carried out under that licence).

2.8 Similarly it is not possible to collect accurate figures on the numbers of embryonic or larval animals used; the number of returns reporting only such 'non-countable' procedures is shown in Table 19 of the annual statistics.

Classifications

2.9 The current classification system (coding lists) dates from 1995, and was modified in 1999 in

those areas relating to:

- source of animals;
- production and breeding,(to produce genetically modified (GM) animals or harmful mutants (HM);
- toxicology; and
- legislation.

During the collection and verification process, forms that have been recognised as being incorrectly coded are referred back to the licensees for correction.

2.10 The format of information provided relating to the latest calendar year broadly follows that used for the publication of previous statistics relating to the previous calendar year. Where particular types of procedures have been disallowed under administrative provisions subsequent to the inception of the Act, footnotes indicate this.

Definitions of genetic modification (GM) and harmful mutant (HM)

2.11 GM animals are those whose genetic characteristics have been altered using genetic engineering. This involves the direct manipulation of the animal's DNA using biotechnology. This could involve the removal of certain genes (called 'knock-outs'), or adding genetic material from another species to the host (called 'transgenic'). Other ways of more indirect genetic modification have been practiced for centuries, through selective or cross breeding, but this is not what is meant by GM in this report.

2.12 HM animals possess one or more genes that have undergone mutation, which involves a change in their genetic structure. This may be the result of the application of chemicals or radiation in order to cause the mutation, and is distinct from GM where genetic material is either inserted or removed. Further details of the coding of GM and HM animals are given in the form notes (see para 6.1 below).

Legal purpose of the statistics

2.13 The annual statistics publication relates to scientific procedures performed using living animals subject to the provisions of the Animals (Scientific Procedures) Act 1986. The purpose of the publication is to meet the requirements of section 21(7) of the Act:

"The Secretary of State shall in each year publish and lay before Parliament such information as he considers appropriate with respect to the use of protected animals in the previous year for experimental or other scientific purposes".

2.14 The Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012, section 21A, provides additional provisions on statistics and reporting, in order to comply with EU Directive 2010/63/EU. These provisions will affect the substance and content of the statistics collection from 2014 onwards, and will be described in detail in the July 2014 statistical release and user guide.

Legal definition of a regulated procedure

2.15 The 1986 Act defines a regulated procedure as follows

> (i) A "regulated procedure" is defined by Section 2(1) of the Act as "any experimental or other scientific procedure applied to a protected animal which may have the effect of causing that animal pain, suffering, distress or lasting harm".

(ii) "Pain, suffering, distress and lasting harm" encompass any material disturbance to normal health (defined as the physical, mental and social well-being of the animal). They include disease, injury and physiological or psychological discomfort, whether immediately (such as at the time of an injection) or in the longer term (such as the consequences of the application of a carcinogen).

(extract from Guidance on the Operation of the Animals (Scientific Procedures) Act 1986)

2.15 The threshold at which regulation is applied has been agreed at EU level to be the skilled insertion of a hypodermic needle. This means for example that even a study that involves only the taking of blood samples is 'a procedure', for the purposes of the annual statistics.

2.16 Under this Act any scientific procedure carried out on any living vertebrate animal, or one species of octopus *(Octopus vulgaris)*, which is likely to cause that animal pain, suffering, distress or lasting harm is a regulated procedure requiring licence authority. Recognised veterinary, agricultural or animal husbandry practice and the administration of medicines under an Animal Test Certificate granted under Veterinary Medicines Regulations 2008 are excluded from the controls of the 1986 Act.

2.17 The system of control under the 1986 Act is explained in detail in Appendix A of the annual statistics publication. Some information previously included is now published via the Annual Report of the Home Office Animals in Science Regulation Unit available at:.
https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2012

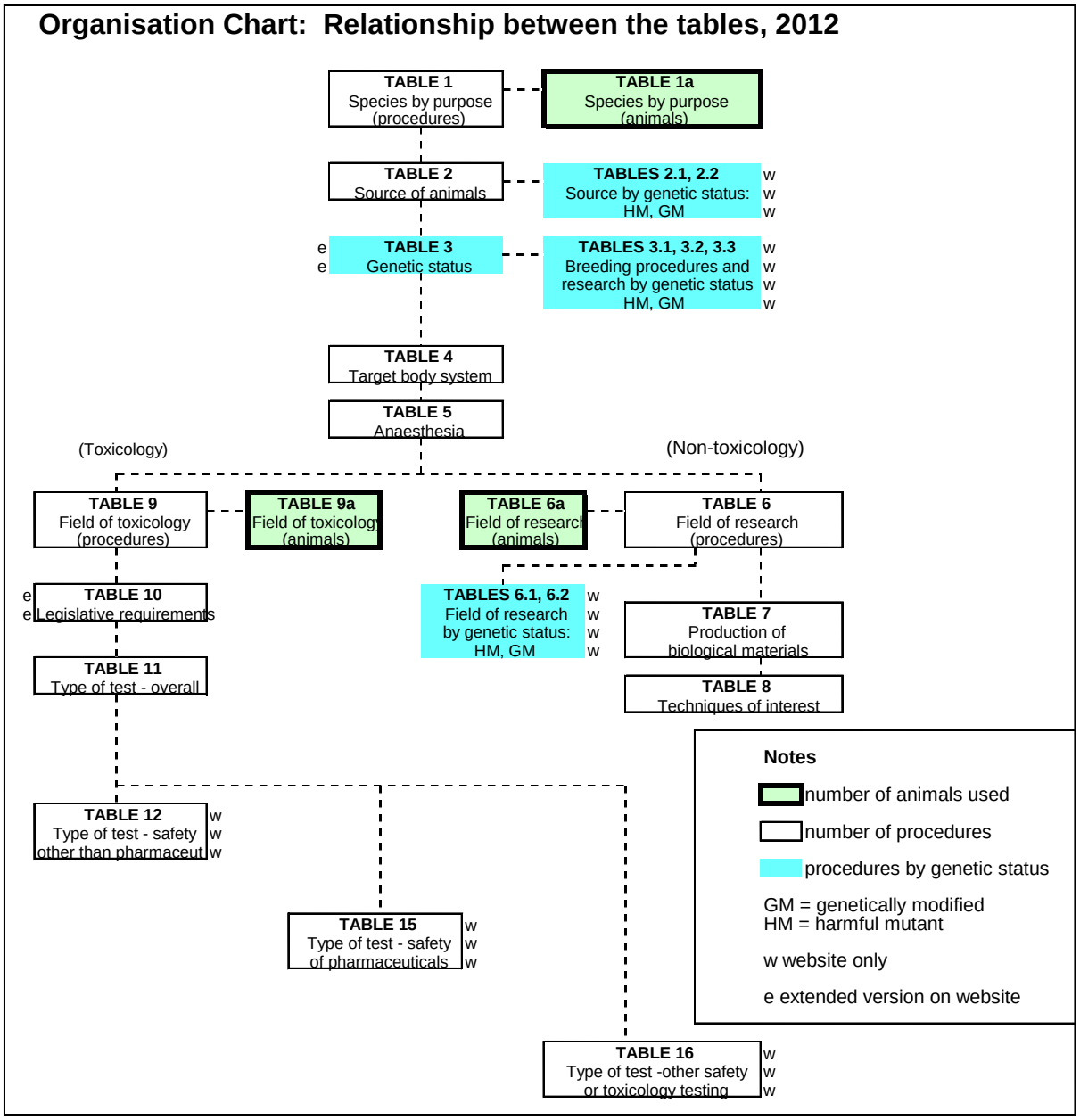
Explanatory notes for published tables

Definitions

All tables refer to numbers of scientific procedures started on adult animals in the calendar year, unless indicated otherwise. Tables suffixed with an 'a' (e.g. Tables 1a, 6a, 9a) relate to numbers of animals used.

Symbols used in tables

..	not available	**-**	nil
NA	not applicable	**r**	revised



Explanatory Notes for published tables (continued)

Species of animal
3.1 Most tables, except the online Time Series tables, are classified by species of animal. The full classification is used in Tables 1, 1a, 6, 6a, 9 and 9a, but the other tables use a condensed classification. All the tables except 1a, 6a and 9a give the number of procedures. Tables 1a, 6a, and 9a give the actual number of animals used for the first, and usually only, time in the latest calendar year. In these tables the classification is according to the first use The list of species or categories of animals is selective to avoid undue complications; when collective terms are used it is because previous experience suggests that the category will contain a relatively small number or because further breakdown is of little interest. In several of the tables, rows that are completely zero have been omitted and if a species is not mentioned it is because the row or rows pertaining to that species is blank.

Genetic status of animal
3.2 Table 2 (source), Table 3 (genetic status), and Table 6 (non-toxicological work by field of research) are subdivided to give more information about animals with abnormal genetic constitutions. Table 2 shows procedures using all animals; Table 2.1 shows the number of procedures using animals with harmful (but naturally occurring) genetic defects and table 2.2 shows the number of procedures using genetically modified animals. Table 6 follows the same pattern. Table 3 is subdivided into three supplementary tables (3.1, 3.2 and 3.3) to present in detail the use of normal animals, harmful mutants (HM), and genetically modified (GM) animals respectively, in breeding programmes or research.

Primary purpose (Table 1)
3.3 The use of animals for regulated procedures is limited by section 5(3) of the Act to one of the following primary purposes:

(i) **Fundamental biological research**; carried out with the primary intention of increasing knowledge of the structure, function and malfunction of man and other animals, or plants. Such studies may be aimed solely at an increase in knowledge, application of that knowledge being beyond the scope of the investigation, or with a view to providing a practical solution to a medical or veterinary problem once the issues are more clearly defined and understood. This category includes physiological, pathological, pharmacological, genetic and biochemical studies, including toxicological evaluation.

(ii) **Applied studies - human medicine or dentistry, and veterinary medicine**; consisting of research into, development of and quality control of products or devices, including toxicological evaluation and safety or efficacy testing.

(iii) P**rotection of man, animals or the environment**; by toxicological or other safety or environmental evaluation. This category is intended to cater for toxicological work that is not related to either fundamental research or the solution of medical and veterinary problems as such (see (i) and (ii) above), but also includes some non-toxicological procedures e.g ecological studies may be included. This category is further divided into a number of subgroups (listed in Tables 9 and 9a). These are largely self-explanatory but the following notes may be helpful in understanding the figures:

(a) While any one substance may be used in industry or in the home, or may be an environmental pollutant, a herbicide or a pesticide, the project licence holder classifies the procedure in accordance with the particular context of the procedure and the expected primary use of the product;

(b) Animal pesticides (distinct from plant pesticides) are not included amongst the types of substances listed, because a substance intended to kill pests that infest or attack animals

would be regarded as a veterinary product. These are included in the appropriate body-system group covered by primary purposes described in (ii) above;

(c) Many of the procedures recorded under this category are required by UK law or by the laws and regulations of countries in which it is intended to use the substance concerned;

(d) The term 'food additives' covers substances deliberately added to food as preservatives, artificial colourants or flavouring agents but not studies on the nutritive value of food, accidental contamination or infection of food, or medicines administered to animals or humans in food.

(iv) **Education and training;** these categories include procedures carried out under project licences for the purposes of education or training under the 1986 Act. They also include the killing of animals by methods not included in Schedule 1 to the 1986 Act, if the killing takes place for educational purposes at a designated establishment. Such killing may be authorised to provide, for example, tissues subsequently used for education or training. The use of animals for the acquisition of manual skills is currently permitted only for training in microvascular surgery, and at present this is always carried out under general anaesthesia, without recovery.

(v) **Forensic enquiries**; may refer to animal use in human or veterinary enquiries relevant to potential legal proceedings.

(vi) **Direct diagnosis;** investigation of disease including investigating suspected poisoning. This caters for procedures carried out under the 1986 Act for the purpose of diagnosing disease in an individual human or animal patient or a group of such patients. There is no research function: these are essentially applied studies, predominantly involving the production of biological reagents, for example antibodies and clotting factors.

(vii) **Breeding**; a category for recording the production and breeding of animals with harmful genetic defects, and genetically modified animals. The numbers recorded in this category include those animals that are identified as possessing a harmful mutation or are genetically modified, but not used subsequently on procedures that are recorded elsewhere in the tables. The numbers also include some genetically normal animals that were subjected to regulated procedures such as tissue sampling or hormonal administration for the purpose of regulated breeding programmes (see also Tables 3, 3.1, 3.2, 3.3).

Source of animals (Tables 2, 2.1, 2.2)

3.4 Sections 7 and 10(3) of the Act require, unless a specific exemption is granted, that certain animals, listed in Schedule 2 to the Act, be obtained from designated breeding or supplying establishments certified as such by the Secretary of State. The species so listed during the calendar year were: mouse, rat, guinea-pig, hamster, gerbil, rabbit, cat, dog, ferret, primate, quail (Coturnix coturnix) , any frog of the species Xenopus (laevis and tropicalis) or Rana (temporaria and pipiens) and zebra fish; also pigs (if GM), and sheep (if GM). Normal pigs and normal sheep remain outside the scope of this schedule. The source of these species is tabulated according to whether it is within the UK, within the remainder of the EU, within certain Council of Europe (but non-EU) countries that are signatories to the European Convention for the Protection of Vertebrate Animals used for Experimental and Other Scientific Purposes (ETS 123)**,** or elsewhere. Animals that originate from non-designated sources, such as overseas breeding centres, but that are acquired by the project licence holder via a designated supplying establishment in the UK, are reported under the heading "Animals acquired from other designated breeding or supplying establishments in the UK."

3.5 Table 2 lists numbers of procedures by source of animal, as described above. Tables 2.1 and 2.2 list

procedures by source for animals with a harmful (but naturally-occurring) genetic defect, and GM animals, respectively. The use of Schedule 2-listed species from non-designated sources in the UK, or from Europe or elsewhere, is subject to prior approval by the Home Office. Such use would be justified on the basis of scientific need or lack of availability of appropriate animals from designated breeding or supplying establishments.

Stage of development, genetic status, and breeding (Tables 3, 3.1, 3.2, 3.3)

Stage of development

3.6 Details of procedures on animals in foetal, larval or embryonic form are collected but not shown in any of the published tables, This is because it may be impracticable in some cases to count such procedures, e.g. a foetus resorbed during gestation, or fish fry that are very small and fast-moving.

Genetic status

3.7 Only the number of animals in which a harmful genetic defect actually manifested itself has been recorded for spontaneously arising mutants. All GM animals are recorded. Additional information on counting animals in those categories is provided in Annex A at the end of Appendix B.

3.8 The detailed online Table 3.1 shows the use of genetically normal animals in breeding programmes for both HM and GM animals. The number of procedures is shown for:

- normal animals used to generate founder GM animals (which themselves will be further used in breeding programmes);
- normal animals within GM breeding colonies; and
- normal animals within breeding colonies of animals with naturally-occurring harmful mutations.

3.9 The detailed online Tables 3.2 and 3.3 show the use of HM and GM animals respectively in breeding programmes or research. The structure of these two tables is similar. They show, respectively for HM and GM animals:

- procedures undertaken for maintenance of the breeding colony;
- procedures undertaken for research analysis *post mortem*);
- further regulated procedures, following on from the breeding programme;
- procedures used for production; and
- procedures for toxicological (safety evaluation) purposes.

Breeding

3.10 The breeding of animals with potentially harmful genetic defects or GM animals is a regulated procedure under a project licence. Animals that are identified as HM or GM animals may be used for further breeding or used subsequently in procedures. The numbers also include some genetically normal animals that were subjected to regulated procedures such as tissue sampling or hormonal administration for the purpose of regulated breeding programmes.

3.11 The classifications of procedures concerned with breeding distinguish between:

(a) animals used to generate founder GM animals for novel transgenic lines, chimeras or clones;
(b) GM animals generated by recognised husbandry methods for maintenance of a breeding colony;
(c) GM animals used in research programmes not concerned with breeding;
(d) animals with a harmful mutation generated by recognised husbandry methods for the maintenance of breeding colonies;
(e) HM animals used in research programmes not concerned with breeding.

Target body system (Table 4)
3.12 Some of the headings in the tables are self-explanatory but, for the others, further explanation is given below.

Abbreviated title	Description: studies in which interest centres on:
Nervous	The central or peripheral nervous systems, other than the special senses
Senses	Sight, hearing, smell, or taste
Alimentary	The alimentary (including liver) and excretory systems
Musculo-skeletal	The skeletal or muscle system
Immune and reticulo-endothelial	The understanding and operation of the immune system
Other system	A single body system not separately listed in the table
Multiple systems	More than one system of primary interest
System not relevant	The system or systems affected were not predictable or not relevant

Use of anaesthesia (Table 5)
3.13 The codes for anaesthesia distinguish procedures involving one or more stages in which there was anaesthesia with recovery and from procedures in which the only anaesthesia was terminal. They also include the use of local or regional anaesthesia. The categories are listed below:

(a) No anaesthesia used throughout the procedure; this will include procedures without anaesthesia even where the subject animal may have been killed by use of an anaesthetic overdose at the end of the procedure. It also includes studies of potential anaesthetic agents;
(b) General anaesthesia with recovery;
(c) Local or regional anaesthesia;
(d) General anaesthesia without recovery, at the end of the procedure only;
(e) General anaesthesia without recovery, throughout the procedure.

3.14 The killing of an animal by the administration of an overdose of an anaesthetic agent (a recognised humane method as cited in Schedule 1 to the Act) is not a regulated procedure and is not recorded as such in the above table.

3.15 The use of neuromuscular blocking agents (NMBA) is uncommon and for this reason such use is not shown in the table (except as a footnote).

Type of procedure
3.16 The tables are divided into two groups:

> **Fundamental and applied studies other than toxicology (Tables 6–8);**
> **Toxicity tests, or other safety or efficacy evaluation (Tables 9–16).**

3.17 If the purpose was non-toxicological, the licensee was asked to specify the field of research (Table 6), the nature of the procedure with regard to production and breeding (Table 7) and whether the technique was identified as being of particular interest (Table 8).

3.18 If the purpose of the procedure was toxicological, the licensee was asked to report on the field of safety testing or efficacy evaluation (Table 9), the type of test or procedure (Table 11), and the legislative requirements (if any) under which the procedure was performed (Table 10).

3.19 The two strands of reporting are mutually exclusive (as shown in the flowchart and form notes) and it is not possible, for instance, to identify procedures using a technique of particular interest if the purpose of the procedure was toxicological.

Fundamental and applied studies other than toxicology

3.20 This group of tables is sub-divided into three main areas of interest:

(i) **Field of research** (Tables 6, 6a, 6.1 and 6.2)

The headings are self-explanatory, but the following should be noted:

(a) pharmaceutical research and development excludes anti-cancer agents, where work is listed separately later in the table under 'cancer research';
(b) ecology excludes work done in toxicology and other safety evaluation;
(c) tobacco and alcohol research lists only those procedures done for research on the effects of tobacco or alcohol, and not those where these substances are used as experimental tools or standards; note also that tobacco *safety* procedures would be reported in Table 9.

(ii) **Production of biological materials** (Table 7)

The table shows procedures for:

(a) production and maintenance of infectious agents (excluding those causing neoplasms);
(b) production and maintenance of vectors, e.g. parasites;
(c) production and maintenance of neoplasms;
(d) the ascites model for the production of monoclonal antibodies;
(e) initial immunisation for subsequent *in vitro* or *in vivo* production of monoclonal antibodies;
(f) production of polyclonal antibodies;
(g) production of other biological material, e.g. plasma, tissues.

(iii) **Techniques of particular interest** (Table 8)

This table provides a selective list that identifies those procedures in which a technique is of itself of particular interest as, for example, the application of a substance to the eye or exposure to ionising radiation. The procedures recorded in this table do not include those undertaken for toxicology or safety evaluation. However, few of these techniques would be used in routine regulatory toxicology or safety assessments.

Toxicity tests, or other safety or efficacy evaluation

3.21 This group of tables is sub-divided into four main areas of interest:

(i) **Safety and efficacy evaluation** (Tables 9, 9a)

Some of the subdivisions have been described above at paragraph 3.3(iii) with regard to general safety or efficacy evaluation (e.g. pollution, agriculture, industry, household, food additives) but the category also includes work done for pharmaceutical safety and efficacy evaluation, and some other purposes such as toxicology research.

In line with current policies the reported figures show no procedures to test or develop cosmetics or cosmetic ingredients, nor procedures using animals in research on tobacco.

(ii) **Legislative requirements** (Table 10)

This identifies medical/dental and veterinary categories. These include:

(a) procedures used in the initial development and selection of such products;
(b) those required to satisfy specific legislation (medical and non-medical) such as the Medicines Act 1968 and/or equivalent overseas and international legislation or regulations for purposes such as the intention of registration or the intention of presenting batch quality control data; and
(c) those carried out for other reasons.

The legislation is divided into seven groups:

(a) UK legislation only;
(b) legislation specific to one EU country only (excluding the UK);
(c) general EU requirements, including the European Pharmacopoeia;
(d) non-EU member country of Council of Europe legislation;
(e) legislation of other countries;
(f) any combination of (a)-(e);
(g) purposes other than legislative requirements.

The following are examples of specific legislative requirements that may be included:

Medicines Act 1968;
Workplace safety, e.g. Health and Safety at Work Act 1974, COSHH Regulations;
Substances used in agriculture, e.g. Control of Pesticides Regulations 1986; EU Pesticides Directives;
Substances used in foodstuffs, e.g. Food Safety Act 1990.

(iii) **Specific types of toxicity tests** (Table 11)

The table shows:

(a) acute and subacute dose ranging or limit setting lethal toxicity tests;
(b) acute quantitative lethal toxicity tests;
(c) acute and subacute non-lethal clinical sign toxicity tests;
(d) subchronic and chronic toxicity tests;
(e) carcinogen/teratogen/mutagen tests;
(f) other reproductive toxicity tests;
(g) tests for clinical signs in the eye;
(h) tests for clinical signs on the skin, including irritation or sensitisation;
(i) toxicokinetics, pyrogenicity, biocompatibility and other toxicology tests.

(iv) **Tables showing some selected work in greater detail**
There are three further tables that examine some aspects of toxicological work in greater detail
:

Table 12: Non-pharmaceuticals (list A, row 10, codes A01–A06);
Table 15: Pharmaceuticals (list A, row 10, codes A11–A14);
Table 16: Other safety or toxicology (list A, row 10, codes A21–A25).

Using the statistics ✓

4.1 The following list of uses of official statistics was produced (October 2010) by the UK Statistics Authority. The use made of official statistics. A range of the expected uses of the statistics is given below and the examples marked with a tick ✓

i. Informing the general public's choices:
- *a. about investment decisions;*
- *b. about service providers;*
- *c. about lifestyle choices;*
- *d. about the state of the economy, society and the environment ✓e.g. via Parliament & the media; and*
- *e. about the performance of government and public bodies ✓e.g. via Parliament & the media*

ii. Government decision making about policies, and associated decisions about related programmes and projects:
- *a. policy making; and ✓*
- *b. policy monitoring ✓*

iii. Resource allocation – typically by central and local government ✓

iv. Informing private sector commercial choices: ✓
- *a. targeting local markets;*
- *b. targeting households and individuals; and*
- *c. designing market research surveys*

v. Informing public marketing campaigns

vi. Supporting third sector activity:
- *a. lobbying; ✓*
- *b. funding applications ✓*

vii. Facilitating academic research ✓.

Examples of use of the annual statistics

4.2 Below are some examples of uses made of the statistics

Parliamentary debates

Westminster Hall debate 24 February 2009 (24 Feb 2009 : Column 25WH)
http://www.publications.parliament.uk/pa/cm200809/cmhansrd/cm090224/halltext/90224h0004.htm#09022447000459

House of Commons Library Standard Note: SN/SG/2720 animal experiment statistics (Last updated: 19 February 2009) note on animal experiments.

General Committee debate 3 December 2012 on Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012
http://www.publications.parliament.uk/pa/cm201213/cmgeneral/deleg6/121203/121203s01.htm

Replies to Parliamentary questions (PQs)

Replies to around 20 written PQs were provided by the Home Office during 2013. Topics included overall numbers of procedures and a range of questions relating to Wales and Scotland.

Media coverage for the report on 2012 data

BBC
http://www.bbc.co.uk/news/science-environment-23325821

Guardian
http://www.theguardian.com/science/2013/jul/16/research-animals-rises-4m-procedures

Users
As well as Parliament, the media, the general public and individual licensees, there is a wide range of organisations with an interest in these statistics; some examples are listed below
(The list is illustrative and not meant to be exhaustive)

Animals in Science Regulation Unit, Home Office https://www.gov.uk/research-and-testing-using-animals

APC Animal Procedures Committee

NC3Rs NC3Rs - National Centre for the Replacement, Refinement and Reduction of Animals in Research

FRAME FRAME: Fund for the Replacement of Animals in Medical Experiments

BUAV http://www.buav.org/

National Anti-Vivisection Society NAVS

UAR Understanding Animal Research

RSPCA www.rspca.org.uk

Research funders e.g. Wellcome Trust (www.wellcome.org) and Medical Research Council (www.mrc.ac.uk)

European Commission http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm

LAVA Laboratory Animals Veterinary Association

LASA Laboratory Animal Science Association

IAT Institute of Animal Technology

Federation of European Laboratory Animal Science Associations www.**felasa**.eu

Collection procedures, coverage, confidentiality and quality assurance

Collection and coverage

5.1 The statistics are compiled from returns, submitted by project licence holders at the end of each year, or on the termination of the licence when this occurs during the year. A copy of the form instructions can be found in this user guide, including the detailed definition of a procedure, and descriptions of the standard coding lists used for describing procedures. Each procedure (which may consist of several stages) for a given purpose on an animal is counted as one returnable procedure for the year in which it commenced. A study involving a procedure using a number of animals is counted once for each animal. Where an animal that has recovered fully from a completed procedure is used again for a further procedure it is counted as a separate procedure, but the animal itself is not re-counted. The circumstances in which this re-use of an animal is permitted are limited.

5.2 Licence holders are required, as a condition of their licence, to submit a return even if no work has been undertaken (nil returns). A record is kept of all licensees from whom returns have been received. Those who fail to do so are reminded of their obligation under the Animals (Scientific Procedures) Act 1986.

5.3 To ensure that the published data are as complete as possible the Home Office will not publish the statistics unless the number of missing returns represents less than 0.5 percent of all the returns expected.

Confidentiality

5.4 Detailed information on the work of individual project licence holders is not readily identifiable in this publication. Where a further breakdown of the 'other' species categories are not given in the commentary this is to safeguard the confidentiality of the establishment and the licence holder.

5.5 The current classification system (coding lists) dates from 1995, and was modified in 1999 in those areas relating to the source of animals, production and breeding to produce genetically modified (GM) animals or harmful mutants (HM), toxicology and legislation. During the collection and verification process, forms that have been incorrectly coded are referred back to the licensees for clarification and correction as needed. Further details of the coding of GM and HM animals are given in the form notes para 6.1.

Quality assurance

5.6 There is a wide variety of quality assurance checks, carried out with the expert assistance of colleagues in the Animals in Science Regulation Unit, and with follow up contact with licensees as needed, for example:

- checking for duplicates
- checking that all licensees expected to provide returns have done so (all licensees providing returns for previous year's exercise [where not revoked in the previous year] plus all licences granted during the year)
- identifying forms containing invalid or missing data
- identifying invalid combinations of codes (e.g. Schedule 2 species indicated by Row5 entry but Row 5 entry is not a Schedule 2 species)
- identifying returns containing unusual or rare combinations of codes
- checking data on specific issues e.g. all returns indicating use of species covered by the Convention on International Trade in Endangered Species (CITES) are checked
- variance checking i.e. investigating substantial changes in figures compared with the previous year

Reference materials: Form Notes

6.1 A copy of the form notes is given below and overleaf

Animals (Scientific Procedures) Act 1986

NOTES FOR RETURN OF PROCEDURES

For each project licence held the licence holder should complete a separate form by 31 January for all regulated procedures on living animals started in the previous year (including the work of all personal licensees performing regulated procedures on their project) as part of the conditions for the licence. NB Failure to provide a return constitutes a breach of the Act and can be considered as an infringement. This can affect other licences held and any future licence applications.

NOTES ON COMPLETING THE FORM – a checklist

(i) discard any previous versions of these guidance notes or of the form.

(ii) make sure you are clear what is meant by a 'regulated procedure' - see definition below.

(iii) if you have carried out any work using harmful mutant or genetically modified animals, please first read Annex B at pages 6-8 of these guidance notes.

(iv) if the procedures started included the re-use of animals (irrespective of whether the first use was in 2013 or earlier) please first read the definitions of re-use under ROW 15 at page 5 of these guidance notes.

(v) complete SECTION 2 one column at a time in line with the sequence shown by the arrows. For each entry in a column (i.e. each box) select the most appropriate code from the code list for that ROW, using the code lists at pages 2-3 of these guidance notes, entering only one code in any one box. Complete as many columns as necessary to describe fully the use of different groups of animals in a particular procedure.

(vi) each completed column should record all the procedures for any animal or group of animals of the same species which are described by that particular combination of codes. If your project requires more than 50 columns to describe it, please contact the Animals in Science Regulation Unit.

(vii) where procedures are carried out on multiple sites under a licence, please check that all procedures have been included.

(viii) complete the declaration in SECTION 1 and return the form as soon as possible to your Home Office contact.

Definition of a regulated procedure

A 'regulated procedure' is defined by Section 2 (1) of the Act as "any procedure applied to a protected animal for a qualifying purpose which may have the effect of causing the animal a level of pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice". The 'use' of a protected animal under project licence authorities extends from the time the first regulated procedure is applied to the animal up to the time when the observations, or the collection of data (or other products) for a particular scientific purpose (usually a single experiment or test), are completed. This is the use which should be reported as a single procedure in ROW 13 of the form. Continued use between more than one project licence protocol should be returned as a single procedure. Each re-use as identified in the project licence should be reported as additional procedure(s). You may find it helpful to refer to paragraphs 2.6 to 2.33 of the Home Office Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 (Published in March 2000 by HMSO, reference HC321 http://www.archive.official-documents.co.uk/document/hoc/321/321.htm) before completing this section.

Queries

If you have any queries about how to complete this form please contact the ASRU Business Support Team by email on ROPReturns@homeoffice.gsi.gov.uk or by phone on 020 7035 0583/8625.

THANK YOU FOR YOUR ASSISTANCE. **Further guidance and code lists overleaf**

CODE LISTS

ROW 1: SPECIES

Select the appropriate code from the list below.

MAMMAL

R0 use this code for rodenticide field trials only. **There is no need to complete the rest of the column.** (you must provide a covering letter giving estimates of the number of each species which may have undergone pain, suffering, distress or lasting harm during the field trials.)
R1 Mouse
R2 Rat
R3 Guinea-pig
R4 Hamsters (Syrian) (Mesocricetus auratus)
R5 Hamsters (Chinese) (Cricetulus griseus)
R6 Gerbil
R9 Other rodent (*please append a note indicating species used*)
L1 Rabbit
C1 Cat
C2 Dog - beagle
C3 Dog – Greyhound
C4 Dog – other including cross bred
C5 Ferret
C9 Other carnivore (*please append a note indicating species used*)
U1 Horse, donkey and cross-bred equids
U2 Pig
U3 Goat
U4 Sheep
U5 Cattle
U6 Deer
U7 Camelid
U9 Other ungulate (*please append a note indicating species used*)

PRIMATE

P1 Prosimians (Prosimia)
P2 Marmoset and tamarins
P3 Squirrel monkey
P5 Cynomolgus monkey (Macaca ascicularis)
P6 Rhesus monkey (Macaca mulatta)
P7 Vervets chlorocebus
P8 Baboons
P9 Apes
P10 Other species of non-human primates (*please append a note indicating species used*)
J9 Other mammal (*please append a note indicating species used*)

BIRD

T1 Domestic fowl
T2 Turkey
T3 Quail (Coturnix coturnix)
T4 Quail (spp. other than Coturnix coturnix)
T9 Other bird (*please append a note indicating species used*)

REPTILE

D1 Any reptilian species (*please append a note indicating species used*)

AMPHIBIAN

M1 Rana temporaria
M2 Rana pipiens
M3 Xenopus laevis
M4 Xenopus tropicalis
M5 Other amphibian species (*please append a note indicating species used*)

FISH

F1 Zebra fish
F2 Other fish (*please append a note indicating species used*)

CEPHALOPOD

F5 Any Cephalopod (*please append a note indicating species used*)

ROW 2: CITES

Animals of endangered species listed in **Appendix 1 of the Convention on International Trade in Endangered Species of Flora and Fauna (CITES)** or in **Annex C.1 to the Council Regulation (EEC) 3626/82(a)** are subject to special controls and information is required on their use. Most species and strains of animals used in the laboratories are NOT included in the CITES lists. Please consult your Inspector for further information.

Select the appropriate code from the list below.

0 the species is **not** so listed.
1 the species used in this procedure is listed in Appendix 1 or Annex C.1. ***(please give both common and Latin name for species)***

Some examples of CITES codes:

0 Common marmosets; macaca spp **except** *M. silenus*
1 Cotton top tamarins (*Saguinus oedipus*);
some birds of prey such as Peregrine falcon (*Falco peregrinus*)

ROW 3: STAGE OF DEVELOPMENT

Select the appropriate code from the list below.

1 Adult animal, free-living (including neonatal and juvenile mammals and newly-hatched birds).
Use this code for Zebra fish fry from 6 days post fertilisation and amphibia from the stage when 4 limbs have developed, including Axolotls.
2 Larval/embryonic/foetal animal. **Do not count these animals – enter "0" in ROWs 13, 14 and 15.**

ROW 4: GENETIC STATUS

Select the most appropriate code from the list below

1 Normal animal
2 Animal with harmful genetic defect (e.g. harmful mutants)
3 Genetically modified animal (e.g. transgenic, knock-out).

Important guidance on coding and counting of harmful mutants or genetically modified animals is given in Annex B.

ROW 5: SOURCE OF ANIMALS

Schedule 2 of the Act lists the following species: any mouse of the species Mus musculus, any rat of the species Rattus norvegicus, guinea-pig, any hamster of the species Mesocricetus auratus or Cricetulus griseus, any gerbil of the species Meriones unguiculatus, any rabbit of the species Oryctolagus cuniculus, cat, dog, ferrets, primate, any bird of the species Coturnix coturnix (quail), any frog of the species Xenopus (laevis and tropicalis) Rana (temporaria and pipiens), zebra fish, pigs if genetically modified and sheep if genetically modified,

Enter:

0 If the species is **NOT** listed in Schedule 2.

For **Schedule 2 species** enter:-

1 If the animals were acquired from within own designated establishment.
2 If the animals were acquired from another designated establishment in the UK (e.g. a university or commercial breeder).
3 If the animals were acquired from non-designated sources in the UK.
4 If the animals were acquired from other countries **within** EU other than the UK (See list at LIST A, ROW 12).
5 If the animals were acquired from member countries of the Council of Europe which are parties to convention ETS 123 (excluding EU member states). See list below.
6 If the animals were acquired from other sources.

Non-EU ETS 123 countries (Code 5 above)

Switzerland
Norway Turkey

ROW 6: ANAESTHESIA

Select the most appropriate numeric code from the list below.

0 **No anaesthesia throughout the procedure.**
Include, procedures without anaesthesia which end by a Schedule 1 method of killing, even if this consisted of an anaesthetic overdose. Use this code also for the study of potential anaesthetic agents.
1 **General anaesthesia with recovery.**
Used at any stage of the procedure irrespective of other uses of anaesthesia.
2 **Local or regional anaesthesia.**
Used at any stage of the procedure.
3 **General anaesthesia without recovery.**
Used at the end of a procedure which did not otherwise involve anaesthesia. (See note below).
4 **General anaesthesia without recovery.**
Used throughout the procedure.

NOTE

If the animal was killed by a method listed in Schedule 1 of the Act using an overdose of an anaesthetic agent, this was not part of the regulated procedure and should not be recorded as such.

ROW 7: NEUROMUSCULAR BLOCKING AGENTS

Select the appropriate code from the list below.

0 No use of neuromuscular blocking agents (NMBA).

1 NMBA used during the procedure at some stage. *(Associated codes for ROW 6 will usually be 1, 3 or 4.)*

ROW 8: PRIMARY PURPOSE OF THE PROCEDURE

Select the appropriate code from the list below.

1 Fundamental biological research:
studies of normal, or abnormal, structure or function of living organisms, organs, tissues, cells or other systems (including fundamental studies in toxicology).

2 Applied studies – human medicine or dentistry:
research, development or quality control of products or appliances, including; toxicological evaluation and safety or efficacy testing

3 Applied studies – veterinary medicine:
research, development or quality control of products or appliances, including; toxicological evaluation and safety or efficacy testing

4 Protection of man, animals or environment by toxicological or other safety or environmental evaluation (excluding medical or veterinary products or appliances). This category is intended to cater for toxicological work which is not related either to fundamental research or to the solution of medical or veterinary problems as such. Ecological studies may be included here with the appropriate codes in ROWs 10-12: A codes for toxicological testing or B codes for other investigative studies.

5 Education

6 Training:
use of animals in acquisition of manual skills is permitted in microsurgery training only.

7 Forensic enquiries:
human or veterinary.

8 Direct diagnosis:
procedures for specific detection of human or veterinary pathogens or production of diagnostic reagents.

9 Breeding:
of harmful mutants or genetically modified animals.
Before selecting this code please read the guidance in Annex B. If using this code ROW 11 must be B61, B62, or B64.

ROW 9: BODY SYSTEM

Select the code from the list below which most closely describes the **primary** target body system for the procedure.

01 Respiratory
02 Cardiovascular
03 Nervous (work directed towards central or peripheral nervous systems other than the special senses)
04 Special Senses (sight, hearing, smell, taste)
05 Alimentary (including liver) and excretory
06 Skin
07 Musculo-skeletal
08 Reproductive
09 Immune and reticulo-endothelial
10 Other system (where the target was a single system not listed)
11 Multiple systems (where more than one system was of primary interest) e.g. respiratory and immune system
12 System not relevant (where the system or systems affected were not predictable or not relevant) e.g. safety studies

ROW 10, 11 & 12

Codes from EITHER list A OR LIST B should be used to complete these rows within a column. A mixture of A and B codes within a column is not permitted.

Use list A if the primary purpose of the procedure described in the column was a toxicological or other regulatory or safety purpose (including efficacy, quality control, ADME).

Use list B for any other primary purpose.

LIST A, ROW 10

TOXICOLOGY OR OTHER SAFETY OR EFFICACY EVALUATION

If the procedure was carried out for a toxicological or other safety-related purpose (including efficacy, quality control, or other regulatory purpose), select the most appropriate code from the list below.

A01 Environmental pollution
A02 Substances used in agriculture
A03 Substances used in industry
A04 Substances used in the household
A05 Food additives other than those administered in food for health purposes
A06 Foodstuffs other than additives
A07 Cosmetics and toiletries - finished products
A08 Cosmetics and toiletries – ingredients

PHARMACEUTICAL SAFETY/EFFICACY EVALUATION (INCLUDING BIOLOGICAL PRODUCTS, E.G. CELLS)

A11 Safety testing
A12 Efficacy testing
A13 Quality control
A14 Absorption, Distribution, Metabolism and Excretion (ADME) and residue studies

OTHER PURPOSE

A21 Fundamental research in toxicology
A22 Tobacco safety testing (inducing alternatives)
A23 Safety/Efficacy testing of medical appliances or devices
A24 Method development or validation
A25 Other toxicological purpose - please describe the procedure and its purpose in a separate note

LIST A, ROW 11

TYPE OF TEST OR PROCEDURE

If the procedure was carried out for a toxicological or other safety-related purpose (i.e. you have used a code from A01– A25 in ROW 10), select the code from the list below which describes the procedure most accurately. The OECD test references are examples and are given only for guidance.

A30 Acute quantitative lethal toxicity test (LD50).
A31 Acute quantitative lethal concentration tests (LC50) (OECD 403 or 203).
A32 Acute limit-setting, or dose-ranging lethal toxicity tests.
A33 Acute oral toxicity test (e.g. OECD 420, OECD 423, OECD 425). Includes such tests as Fixed Dose Procedure, Acute Toxic Class method, Up and Down method, Maximum Non-Lethal Dose or Maximum Tolerated Dose.
A34 Subacute limit-setting (e.g. OECD 407) or dose-ranging toxicity test, usually 14 to 28 days duration.
A35 Subacute quantitative toxicity test (e.g. OECD 407), usually 14 to 28 days duration.
A36 Subchronic and chronic toxicity tests (e.g. OECD 408, 409, 411, 413, 452) for 90 days or more.
A37 Carcinogenicity tests (e.g. OECD 451)
A38 Genetic toxicology tests (e.g. OECD 474, 475) – includes mutagenicity tests and the Micronucleus test.
A39 Teratogenicity tests
A40 Other reproductive toxicity tests, including multigeneration studies
A41 Tests for clinical signs in eyes (e.g. OECD 405)
A42 Tests for skin irritation (e.g. OECD 404)
A43 Tests for skin sensitisation (e.g. OECD 406). Please indicate if you have used either the Guinea Pig Maximisation Test or the Buehler Assay (OECD 406).
A44 Toxicokinetics (e.g. OECD 417)
A45 Pyrogenicity tests
A46 Biocompatibility tests
A47 Enzyme induction for *in vitro* tests
A48 Immunotoxicology tests
A50 Other toxicology tests – these other tests may include collection of normal tissues such as blood for *in vitro* work, and investigative procedures not compatible with other codes. Please describe the procedure and its purpose in a separate note.

LIST A, ROW 12

LEGISLATIVE REQUIREMENTS

If the procedure was carried out for a toxicological or other safety-related purpose (i.e. you have used a code from A01 – A25 in ROW 10), select the code from the list below which most closely describes the legislative requirements for which the procedure was performed. Note that "legislative requirement" includes a requirement imposed by a product or manufacturing licence of the country concerned.

Where a test was intended to satisfy both UK and other requirements, and involved more animals than the UK minimum requirements, two columns should be used to describe the tests. The first column should record the number of animals used to satisfy UK requirements using Code A91 in ROW 12 and the second column should show the remainder using the most appropriate Code (A92 or A93) in ROW 12.

Dose-ranging or other types of preliminary studies should also be classified as having a legislative requirement, using the same code as for the related definitive study.

A91 Procedures performed to meet UK legislative requirements only

A92 Procedures performed to meet national legislation specific to only one EU member state, excluding the UK (see list below).

A93 Procedures performed to meet EU legislative requirements including European Pharmacopoeia

A94 Procedures performed to meet member country of Council of Europe (excluding EU) legislation (see list below)

A95 Procedures performed to meet legislative requirements of other countries e.g. USA, Japan

A96 Any combination of A91-A95 requirements

A97 Toxicity tests carried out for purposes other than meeting legislative requirements - please describe the procedure and its purpose in a separate note

Safety testing to satisfy HSE regulations or similar legislation in other countries should be classified as a legislative requirement choosing from codes A91-A96 as appropriate.

COUNTRY LIST FOR CODE A92 ABOVE AND CODE 4 IN ROW 5

(EU countries other than the UK)

Austria
Belgium
Bulgaria
Cyprus
Czech Republic
Croatia
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Irish Republic
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden

COUNTRY LIST FOR CODE A94 ABOVE

(Council of Europe nations other than EU)

Albania
Andorra
Armenia
Azerbaijan
Bosnia and Herzegovina
Georgia
Iceland
Liechtenstein
Moldova
Monaco
Montenegro
Norway
Russian Fed
San Marino
Serbia
Switzerland
Former Yugoslav Rep. of Macedonia
Turkey
Ukraine

LIST B, ROW 10

FUNDAMENTAL AND APPLIED STUDIES OTHER THAN TOXICOLOGY

If the procedure was carried out for a purpose other than toxicology or safety evaluation, select the code from the list below which best describes the **primary field of research**.

Any of these studies (e.g. clinical medicine, clinical surgery, pharmaceutical R & D, or cancer research) may apply to either veterinary or medical science – the appropriate code for the primary purpose of the animal use would have been given in ROW 8.

B01 Anatomy and developmental biology
B02 Physiology
B03 Biochemistry
B04 Psychology/Behaviour
B05 Pathology
B06 Immunology
B07 Microbiology
B08 Parasitology
B09 Pharmacology
B10 Pharmaceutical Research and Development except for anti-cancer agents (code B17)
B11 Therapeutics
B12 Clinical Medicine
B13 Clinical Surgery including technique development
B14 Dentistry
B15 Genetics
B16 Molecular Biology
B17 Cancer Research including therapy
B18 Nutrition
B19 Zoology
B20 Botany and plant pathology
B21 Agricultural Animal Science not included in codes above
B22 Ecology and environmental studies other than toxicology or other safety evaluation
B23 Animal welfare studies not included in the codes above
B24 Other purpose – if you use this code you must provide a separate note describing the procedure

B31 Tobacco research
B32 Alcohol research
} Use these codes for research on tobacco or alcohol or their constituents. Do not use these codes for use of these substances as pharmacological tools or standards

REMEMBER: Do not mix codes from lists A and B in the same column.

LIST B, ROW 11

PRODUCTION AND BREEDING

If you used a code from B01 to B32 in ROW 10, select a code from the list below which applies to the procedure described in this column.

Production of biological materials

B50 Ascites model for production of monoclonal antibodies
B51 Production and maintenance of infectious agents
B52 Production and maintenance of vectors (e.g. insects)
B53 Production and maintenance of neoplasms
B54 Initial immunisation for subsequent *in vitro* or *in vivo* production of monoclonal antibodies
B55 Production of polyclonal antibodies
B56 Production of other biological material (e.g. plasma, tissues)

Use of Genetically Modified or Harmful Mutant Animals

Please read Annex B (pages 6-8), to ensure correct use of the following codes.

B61 Animals used to generate founder **genetically modified** animals for novel transgenic lines, chimeras or clones. This includes normal animals used in such programmes, e.g. superovulation, vasectomy, pseudopregnant recipients, as well as those animals culled as not being of the appropriate genetic status, but which have undergone regulated biopsy procedures.

B62 **Genetically modified** animals generated by recognised husbandry methods for the maintenance of a breeding colony. This may include normal animals (which have undergone regulated biopsy procedures) produced by using heterozygote parents, as well as animals with a fate as set out in Annex B.

B63 **Genetically modified** animals used in research programmes, where they underwent regulated procedures other than those required for a breeding programme, i.e. where the primary purpose was NOT breeding, i.e. ROW 8 not 9. Normal or wild-type animals used as controls in such research and also subject to regulated procedures should be coded as 1 in ROW 4 and codes B50-B56, or B79 as appropriate, in this list.

B64 **Harmful mutant** animals generated by recognised husbandry methods for maintenance of breeding colonies. This may include animals with a fate set out in Annex B. Normal animals, which have not undergone any other regulated procedures, do not need to be accounted for – see Annex B.

B65 **Harmful mutant** animals used in research programmes, where they underwent regulated procedures other than those required for a breeding programme, i.e. where the primary purpose was NOT breeding, i.e. ROW 8 not 9. Normal or wild-type animals used as controls in such research and also subject to regulated procedures should be coded as 1 in ROW 4 and codes B50-B56, or B79 as appropriate, in this list.

B79 For all other types of animal use, i.e. where GM or HM animals are not involved and the purpose is not production of biological materials, use code B79.

LIST B, ROW 12: PARTICULAR TECHNIQUES

If you used a code from B01 to B32 in ROW 10, select a code from the list below which applies to the procedure described in this column.

B91 Direct interference with any part of the organs of special sense including the brain centres
B92 Direct injection of micro-organisms or material suspected of containing micro-organisms into the brain
B93 Other direct physical interference with the brain
B94 Induction of psychological stress integral to the procedure
B95 Use of aversive training stimuli
B96 Exposure to ionising radiation at doses intended to produce a potentially adverse effect on the animal
B97 Inhalation – **do not use for fish**
B98 Thermal injury } Only use these codes where the study
B99 Physical trauma } was the main purpose of the procedure
B00 None of the above

ROW 13: NUMBER OF PROCEDURES STARTED IN 2013

Please read definition of Procedure on page 1 before completing this row. Each separate use of one animal counts as one procedure. Only procedures started during the year should be included, and not procedures reported in returns for previous years that have continued into 2013.

Do not include foetal, larval or embryonic animals: enter '0' in ROW 13 for these animals i.e. if you have entered '2' at ROW 3. Also enter '0' in ROW 13 if you have entered 'R0' in ROW 1.

ROW 14: NUMBER OF ANIMALS USED FOR THE FIRST TIME EVER IN 2013 (NEVER USED IN A PREVIOUS YEAR)

Where animals are used in more than one separate procedure (i.e. re-use; see below) only the first use counts towards the total which you should enter in ROW 14. This is true whether or not the second and/or subsequent procedures are described in the same column or any other columns of the return or on another return.

ROW 15: NUMBER OF ANIMALS RE-USED IN 2013

In ROW 15 count the number of animals that were re-used (not the number of times they were re-used) in 2013, even if they were re-used before in 2012.

If the figure in ROW 13 (Number of procedures) exceeds the figure in ROW 14 (Number of animals used for the first time in 2013) then some animals must have been re-used.

Definition "Re-use" is a term used where, after completion of one series of regulated procedures, an animal is used again in the same or a different protocol, where a previously unused animal would have equally sufficed to meet the objectives of the second and subsequent use.

(See the HO Website for further guidance on the definition of "Re-use":

http://tna.europarchive.org/20100413151426/http://scienceandresearch.homeoffice.gov.uk/animal-research/publications-and-reference/publications/guidance/use-con-animalsfdfd.html?view=Standard&pubID=606442

Example of re-use An animal is bled three times per year for the collection of normal blood, starting in 2012 and continuing in 2013. For the return on 2012 procedures, the entries for ROW 13, ROW 14, and ROW 15 would be 3, 1, 1 respectively.

For the return of 2013 procedures the entries for ROW 13, ROW 14, and ROW 15 would be 3, 0, 1 respectively.

In the first year the animal is used, it would be counted once in ROW 14, three procedures would be recorded in ROW 13, and one procedure in ROW 15 for the first re-use. In subsequent years, the figures would be ROW 13=3, ROW 14=0 and ROW 15=1. See also the worked example in column 3 on page 6.

CHECKS ON ROW 13, ROW 14, ROW 15

Please check as follows:

- ROW 3 entry is 2, entries at ROW 13, ROW 14, ROW 15 must be zero
- ROW 13 entry is zero, entries at ROW 14, ROW 15 must also be zero
- Sum of entries in ROW 14 and ROW 15 must not exceed the entry in ROW 13.

ANNEX A

EXAMPLES OF COUNTING, RE-USE AND THE USE OF SOME TOXICOLOGY CODES:

Column	1	2	3
Row 1	R2	R1	C1
Row 2	0	0	0
Row 3	1	1	1
Row 4	1	1	1
Row 5	2	2	2
Row 6	1	0	0
Row 7	0	0	0
Row 8	2	4	3
Row 9	11	12	05
Row 10	A14	A03	B18
Row 11	A50	A35	B79
Row 12	A96	A93	B00
Row 13	15	40	90
Row 14	15	40	50
Row 15	0	0	40

Column 1

The whole series of techniques were carried out for a particular purpose and were covered by the description in a single 19(b) protocol sheet of the project licence.

- Fifteen 8-week-old rats (ROW 1 = R2 and ROW 3 = 1)
- Not CITES listed (ROW 2 = 0)
- Normal genetic status (ROW 4 = 1)
- Purchased from a commercial breeder in the UK (ROW 5 = 2)
- Surgical implantation of vascular cannulae with recovery from general anaesthesia (ROW6 = 1), without the use of neuromuscular blocking agents (ROW 7 = 0)
  Subsequently the animals were dosed with a potential drug for cancer therapy (ROW8 = 2 and ROW 9 = 11)
- Three timed blood samples are taken from the cannulae for a pharmacokinetic study (ROW10 = A14)
- Finally the animals were killed by perfusion of fixative under general anaesthesia

Column 2

- 40 genetically normal, six week old mice (ROW1 = R1, ROW 3 = 1 and ROW 4 = 1)
- Purchased from a commercial breeder in the UK (ROW 5 = 2)
- Used in a sub-acute quantitative toxicity test (28 days study) to provide data on a household product (ROW 11 = A35)
- The study was needed to fulfil the requirements for safety evaluation of the product during the manufacturing process when material needs to be moved in bulk, i.e. the testing was required under the regulations relating to the safety of substances used in industry for production within the EU (ROW 8 = 4, ROW 9 = 12, ROW 10 = A03 and ROW 12 = A93).

Column 3

- 90 domestic cats used in feeding studies of feline nutrition (ROW 1 = C1, ROW 2 = 0, ROW 3 = 1, ROW 4 = 1 and ROW 13 = 90)
- Last year 40 new cats were purchased from a designated source in the UK and used (ROW 5 = 2).
- This year 50 more cats were purchased from the same source and used (ROW 5 = 2).
- The regulated procedures do not involve general anaesthesia (ROW 6 = 0).
- The project licence authorises re-use of the animals.
- The 50 cats purchased this year were used for the first time (ROW 14 = 50).
- The 40 cats used last year were re-used in this experiment for the first time during this new calendar year (ROW 15 = 40).

ANNEX B

Explanation of how to code Genetically Modified and Harmful Mutant animals

ROW 4 Overall principles and definition

Harmful Mutants (HM), whether deliberately generated or spontaneously arising, are coded as 2 and Genetically Modified animals (GM), i.e Transgenics, Knockouts etc. and combinations of GM and HM, are coded as 3.

- animals should be counted only once in their lifetime.
- animals should be counted when they are born (or develop to the appropriate stage -see ROW 3), unless they have continued use beyond the breeding protocol, in which case animals should be counted for the final use only on the Return of Procedures for the Project Licence covering the final use (this may mean they are not counted in the year in which they are born).

Exclusions

- Do not count the mating of 2 adults as a procedure, regardless of the genetic status of the adults.
- Animals subjected to somatic mutation, e.g. by vector mediated gene delivery, should be coded as for the starting status in ROW 4, e.g. code as '1' (Normal animal) if they are wild type at the start of the protocol.

ROW 8 How to Code the Primary Purpose for the use of GM and HM animals

Record the primary purpose as "Breeding" (Code 9 in ROW 8) only for

- animals used solely for generation or maintenance of a GM or HM breeding colony, or
- for any animals bred but never used on subsequent protocols, and in these circumstances, GM animals should be coded B61 or B62 in ROW 11 whilst HM animals should be coded B64 in ROW 11.

When not to code as 'Breeding'

The primary purpose recorded at ROW 8 should be coded according to the final protocol, and not coded as 9, in all other circumstances (i.e. where GM and HM animals are bred and then used in a subsequent experimental protocol, whether on the same or a different project licence) – and correspondingly, GM animals should then be coded as B63 in ROW 11, whilst HM should be coded B65 in ROW 11.

ROW 11 How to code Production and Breeding

Harmful mutant and Genetically modified animal use generally falls under B Codes; rarely are they used in safety evaluation work where A codes would be applicable.

Code B79 should be used if none of the previous codes are applicable, ie. animals not used for production of biological materials and neither GM nor HM animals.

How to Code Common Scenarios:

Scenario	How to code		
	ROW 4 Genetic Status	**ROW 8 Primary Purpose**	**ROW 11 Production and breeding**
Generation of founders			
1. Normal animals used to generate founder colony	1	9	B61
2. **GM or HM** animals used to generate founder colony	2 or 3	9	B61
Offspring that are Normal animals and			
3. Not Biopsied	Do not count		
4. Biopsied	1	9	B61 if from founders. B62 or B64 if from breeding colony.
5. Used in further procedures e.g. as controls for GM and HM animals	1	1-8 based on further procedures Do not code as 9	B79
Offspring that are GM or HM offspring and			
6. Used exclusively for maintenance of breeding colony	2 or 3	9	B62 or B64
7. Intercurrent deaths or animals, not used for breeding or anything else. Killed by a Schedule 1 listed method.	2 or 3	9	B62 or B64
8. Animals, whether used for breeding or not, but afterwards killed by a Schedule 1 listed method and tissues used post mortem ie. scientific use made of the animal but outside ASPA	2 or 3	1-8 based on further use Do not code as 9	B63 – B65
9. Continued use on another protocol	2 or 3	1-8 based on further procedures Do not code as 9	B63 or B65

Scenario	How to		
	ROW 4 Genetic Status	**ROW 8 Primary**	**ROW 11 Production and breeding**
GM or HM animals generated on one project licence but transferred to another PPL:			
10. If used only for breeding on the second PPL, count only on the originators return when born.	2 or 3	9	B62 or B64
11. If used in an experiment, do not count at all on the originators return, count on the recipient's final use protocol as appropriate	2 or 3	1-8 based on further procedures Do not code as 9	B63 or B65
12. GM or HM animals generated on a PPL but then exported, (released from ASPA e.g. by a transfer form). Count on the originator's return	2 or 3	9	B62 or B64
Imported GM or HM animals			
13. Imported and used solely for breeding. Count in the year when first obtained	2 or 3	9	B62 or B64
14. Imported and used in a non-breeding procedure	2 or 3	1-8 based on procedures	B63 or B65
Other scenarios:			
15. Used for production of biological material	1 or 2 or 3	1-8 based on procedures	B50 to B56 as appropriate
16. Normal mice crossed with GM or HM mice in breeding protocol	Do not count		
17. All other animals i.e. neither GM or HM, not used for the generation of founders and not used for production of biological materials	1	1-8 Not 9	B79

Details of previous annual publications;

6.2 Electronic copies of the most recent editions can be found at

https://www.gov.uk/government/organisations/home-office/series/statistics-of-scientific-procedures-on-living-animals

and (older editions) can be found at:

http://webarchive.nationalarchives.gov.uk/20100613204643/http://rds.homeoffice.gov.uk/rds/scientific1.html

Annual publications giving detailed figures for scientific procedures under the Animals (Scientific Procedures) Act 1986 were published (by TSO) as "Statistics of Scientific Procedures on Living Animals" as follows:

Year	Command/House of Commons Paper	Year	Command Paper
2012	HC 549		
2011	HC 345		
2010	HC 1263		
2009	HC 317		
2008	HC 800		
2007	HC 933		
2006	Cm 7153		
2005	Cm 6877	1995	Cm 3516
2004	Cm 6713	1994	Cm 3012
2003	Cm 6291	1993	Cm 2746
2002	Cm 5886	1992	Cm 2356
2001	Cm 5581	1991	Cm 2023
2000	Cm 5244	1990	Cm 1574
1999	Cm 4841	1989	Cm 1152
1998	Cm 4418	1988	Cm 743
1997	Cm 4025	1987	Cm 515
1996	Cm 3722		

Detailed figures for experiments on living animals under the Cruelty to Animals Act 1876 were published (by TSO) as "Statistics of experiments on living animals" as follows:

Year	Command Paper	Year	Command Paper
1986	Cm 187	1981	Cmnd 8657
1985	Cmnd 9839	1980	Cmnd 8301
1984	Cmnd 9574	1979	Cmnd 8069
1983	Cmnd 9311	1978	Cmnd 7628
1982	Cmnd 8986	1977	Cmnd 7333

Less detailed information about experiments on living animals for the years prior to 1977 was published in the form of a "Return to an Address of the Honourable the House of Commons".

Further information

6.3 Some sources of further information are detailed below

(i) Information about the work of the Animals in Science Regulation Unit can be found in the latest Annual Report of the Home Office Animals in Science Regulation Unit at https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2011

(ii) Guidance on the Operation of the Animals (Scientific Procedures) Act 1986 at http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm

(iii) Information about the Animal Procedures Committee can be found at https://www.gov.uk/search?q=animal+procedures+committee

(iv) Information about the National Centre for the Replacement, Refinement and Reduction of Animals in research (NC3Rs) can be found at http://www.nc3rs.org.uk/

(v) Information relating to Northern Ireland is published by the Department of Health, Social Services and Public Safety and can be found at http://www.dhsspsni.gov.uk/healthprotection-animalscience

(vi) Information relating to the EU is available on the European Commission's website http://ec.europa.eu/environment/chemicals/lab_animals/reports_en.htm.

(vii) Information on public attitudes to animal testing is available from MORI at http://www.ipsos-mori.com/researchspecialisms/socialresearch/specareas/nhspublichealth/attitudestowardsanimalexperimentation.aspx

Home Office Statistics, July 2014